

**IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION**

CAROLYN HENRY BAYNHAM	:	
	:	
Plaintiff,	:	CIVIL ACTION NO. 1:07-CV-0010
	:	
v.	:	
	:	
THE QUIGLEY CORPORATION; AND WAL-MART STORES, INC.	:	JUDGE THAD HEARTFIELD JURY TRIAL REQUESTED
	:	
Defendants.	:	
	:	
	:	

ANSWER TO PLAINTIFF'S FIRST AMENDED COMPLAINT

NOW INTO COURT, through undersigned counsel, come defendants, The Quigley Corporation (hereinafter "Quigley") and Wal-Mart Stores, Inc., (hereinafter "Wal-Mart") (collectively "Answering Defendants"), who respectfully respond to the averments in Plaintiff's Complaint as follows:

NATURE OF CASE

1. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

THE PARTIES

2. Denied. Following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

3. Admitted in part; denied in part. It is admitted that Quigley is a publicly traded corporation (QGLY), organized and existing under the laws of Nevada, with its headquarters and

principle place of business in Doylestown, PA. The remaining averments of this paragraph are denied as conclusions of law to which no response is required.

4. Admitted.

JURISDICTION

5. Admitted.

FACTUAL ALLEGATIONS

Cold-Eeze

6. Admitted in part; denied in part. It is admitted that Cold-Eeze Nasal Spray is a non-prescription homeopathic cold remedy designed for intranasal administration which is sold in individual boxes with package inserts and a nasal spray container. The remaining allegations are denied.

7. Denied. The active ingredient in Cold-Eeze is *zincum gluconium*. After reasonable investigation, the remaining allegations of paragraph 7 are denied with strict proof demanded.

8. Denied. After reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 8, therefore, such allegations are denied with strict proof demanded.

9. (a-g) Denied. While the studies cited in sub-parts a-g of this paragraph of Plaintiff's Complaint may, in fact, contain the conclusions noted, Answering Defendants specifically deny that they are applicable or relevant to this matter as none of these studies or investigations involved the use of *zincum gluconium*, the active ingredient in Cold-Eeze, or the component parts and/or the Cold-Eeze Nasal Spray product.

10. Denied as stated. The “product information” speaks for itself and exceeds or may exceed that which is alleged.

Plaintiff’s Injuries

11. Denied. Following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

12. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the factual averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

Defendant Quigley’s Actions

13. Denied as stated. The Quigley website speaks for itself and is not or may not be aptly quoted in paragraph 13 and/or is irrelevant to the claims in this case.

14. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that *zinc gluconate*, the active ingredient in Cold-Eeze, causes a serious and permanent loss or impairment of the senses of smell and taste in many people when administered nasally, and/or that Quigley did not reveal relevant information to Plaintiff and other consumers.

15. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Quigley sought to imply that its Cold-Eeze brand product posed any risk to consumers other than those disclosed on the labeling.

16. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

17. Denied. Following reasonable investigation, Quigley is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded. By way of further answer, Quigley incorporates its response to paragraph 9, above.

18. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze in nasal spray form causes anosmia or that Quigley had knowledge of any such risk and failed to disclose same.

19. (a-e) Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze in nasal spray form causes anosmia or that Quigley had knowledge of any such risk and failed to disclose same.

20. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze is a dangerous and defective product. It is further denied that Quigley took any steps to “lull” consumers into buying the product. It is further denied that Quigley took any actions or failed to act because it allegedly knew that public awareness about Cold-Eeze causing anosmia would discourage consumers from purchasing Cold-Eeze or Quigley’s other products.

21. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. Quigley is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied,

with strict proof demanded. By way of further answer, it is specifically denied that Quigley made misrepresentations and omissions concerning the safety of the Cold-Eeze product.

22. Denied. To the extent that the allegations set forth in paragraph 22 of Plaintiff's Complaint are vague, unintelligible and/or incomprehensible, such allegations are denied with strict proof demanded.

23. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that there is any "association between Cold-Eeze and anosmia." It is also specifically denied that Quigley's communications about its products were materially false and misleading.

24. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Quigley was ignorant of whether its labeling or other communications were true in material ways.

25. Denied. Following reasonable investigation, Quigley is without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded. By way of further answer, the averments contained in this paragraph are conclusions of law to which no response is required.

26. Denied. To the extent the allegations of paragraph 26 may constitute conclusions of law, no response is required; by way of further response, after reasonable investigation, the factual averments of paragraph 26 of plaintiff's Complaint are denied with strict proof demanded.

27. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze

causes anosmia, or that Quigley made any misrepresentations or omissions with regard to its Cold-Eeze product.

28. Denied. To the extent the allegations of paragraph 28 may constitute conclusions of law, no response is required. By way of further answer, it is specifically denied that Quigley stopped shipping Cold-Eeze to retailers because of anosmia complaints.

29. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

30. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

Defendant Wal-Mart's Actions

31. Denied. Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in this paragraph, and same are therefore denied, with strict proof demanded.

32. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the factual averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

33. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the factual averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

CLAIMS FOR RELIEF

**COUNT I
Negligence**

34. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 33, inclusive, as if same had been set forth at length.

35. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

36. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze causes loss of smell.

37. (a-e) Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that use of Cold-Eeze can result in a loss of smell.

38. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

39. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze's design is faulty, and/or that its labeling is inadequate.

40. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that use of Cold-Eeze carries the risk of anosmia, or that Answering Defendants failed to make a safe product and/or disclose any risks inherent in the product.

41. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that there is

any association between Cold-Eeze and anosmia, or that Answering Defendants failed to take any step necessary to prevent or minimize harm to Cold-Eeze users.

42. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, Answering Defendants specifically deny that they engaged in misconduct of any kind.

43. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

COUNT II
Strict Products Liability
(Failure to Warn)

44. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 43, inclusive, as if same had been set forth at length.

45. Admitted.

46. Denied. Following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded. By way of further answer, the averments contained in this paragraph are conclusions of law to which no response is required.

47. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

48. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

49. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze causes anosmia or that Answering Defendants had any duty to warn users of same.

50. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

51. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

COUNT III
Strict Products Liability
(Defective Design)

52. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 51, inclusive, as if same had been set forth at length.

53. Admitted in part; denied in part. It is admitted that Answering Defendants expected Cold-Eeze to reach plaintiff without substantial change in the condition in which it was sold and, further, that Answering Defendants expected the product to be used as intended and recommended, however, it is specifically denied that plaintiff used Cold-Eeze Nasal Spray and/or used it in its “as marketed” condition, and same are therefore denied, with strict proof demanded.

54. Denied. Following reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

55. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. By way of further answer, it is specifically denied that Cold-Eeze causes anosmia.

56. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

57. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

58. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

59. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

COUNT IV
Breach of Express Warranty

60. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 59, inclusive, as if same had been set forth at length.

61. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

62. Denied. The averments contained in this paragraph are conclusions of law to which no response is required. It is specifically denied Cold-Eeze causes loss of smell and or loss of taste, or presents a high risk of serious side effects.

63. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

COUNT V
Breach of Implied Warranty

64. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 63, inclusive, as if same had been set forth at length.

65. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

66. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

67. Denied. The averments contained in this paragraph are conclusions of law to which no response is required.

DAMAGES AND REMEDIES

68. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 67, inclusive, as if same had been set forth at length.

69. Denied. Answering Defendants deny all averments in subparagraphs A, B, and C of this paragraph as conclusions of law and, further, after reasonable investigation, Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the averments contained in this paragraph, and same are therefore denied, with strict proof demanded.

AFFIRMATIVE DEFENSES

1. Answering Defendants hereby incorporate by reference thereto each and every averment contained in paragraphs 1 through 69, inclusive, as if same had been set forth at length.

2. At the time any Cold-Eeze product left Answering Defendants' control, the product was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, or labeled.

3. Plaintiff's claims are or may be barred by applicable statute of limitations.

4. At the time any Cold-Eeze product left Answering Defendants' control, the product complied with applicable codes, standards, regulations and specifications established,

adopted, promulgated, or proved by the United States or by the State of Texas, or by any agency of the United States, Texas, or any of the states implicated in this case; the Cold-Eeze product was reasonably fit, suitable, and safe for its intended purpose.

5. Any Cold-Eeze product which is the subject of this litigation conformed precisely in all ways to its specifications and performance standards and posed no danger in its design, manufacture and marketing.

6. Answering Defendants had no duty to warn about any possible dangers that were not known at the time of manufacture and sale of any Cold-Eeze product in question.

7. At the time any Cold-Eeze product left Answering Defendants' control, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which Plaintiff seeks to recover damages without substantially impairing the reasonably anticipated or intended function of the product. Answering Defendants took reasonable precautions consistent with their duties and obligations to protect third parties from any dangers posed by the inherent characteristics of the product.

8. Any Cold-Eeze product at issue in this litigation has been formulated, designed, tested, manufactured, processed, distributed and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, and other applicable laws and any regulations promulgated thereunder. Therefore, Plaintiff's claims are preempted or barred by Federal law pursuant to the Supremacy Clause of the United States Constitution, Article VI, Clause 2, and the laws of the United States.

9. At all times relevant herein, any products purchased from Answering Defendants were sold in a reasonable and prudent matter based upon available medical and scientific

knowledge and further were processed in accordance with and pursuant to all applicable regulations of the Federal Food and Drug Administration.

10. Based on the state of scientific, medical and technological knowledge at the time they were marketed, the product identified in the Complaint was reasonably safe for its normal and foreseeable uses. In light of the existing reasonably available medical, scientific, and technological knowledge, Answering Defendants could not have known of design characteristics, if any, that allegedly caused the damages Plaintiff complains of, or the alleged risk of such characteristics.

11. To the extent there were any adverse effects associated with the use of the Cold-Eeze product which is the subject of this action, of which Answering Defendants knew or should have known and which gave rise to a duty to warn, Answering Defendants at all times discharged its duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations consistent with the existing state of medical and scientific knowledge. In the alternative, Answering Defendants had no duty to directly warn persons concerning risks, if any, associated with the use of said product.

12. Any Cold-Eeze product described in the Complaint was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause Plaintiff's alleged damages.

13. The benefits of the Cold-Eeze product outweigh the risk of danger or harm, if any, inherent in the product.

14. Answering Defendants' advertisements, if any, with respect to the Cold-Eeze product were not falsely misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Texas Constitutions.

15. Answering Defendants' communications and/or interactions within the United States Food and Drug Administration or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine in the First Amendment to the United States Constitution.

16. Plaintiff's claims against Answering Defendants are barred by the Learned Intermediary Doctrine.

17. Plaintiff's claims are barred by the doctrines of release, unclean hands, laches, waiver, satisfaction and accord and/or estoppel.

18. Plaintiff's claims are barred, in whole or in part, by the laws of other jurisdictions.

19. Plaintiff's claims are barred to the extent the injuries alleged in the Complaint were caused or enhanced by pre-existing or unrelated medical or psychiatric conditions or idiosyncratic reactions to the product.

20. Plaintiff failed to give notice of any alleged breach of any warranty.

21. There were no warranties, either expressed or implied, between Plaintiff and Answering Defendants.

22. Answering Defendants breached no warranties, either expressed or implied, which may have existed between them and Plaintiff.

23. Plaintiff has not suffered compensable injuries or damages, and, therefore, has no standing to assert any cause of action against Answering Defendants.

24. With respect to each and every purported cause of action, the acts of Answering Defendants were, at all times, done in good faith and without malice.

25. Plaintiff failed to state a claim upon which attorneys' fees can be awarded.

26. Answering Defendants incorporates all those defenses available under Texas product liability law or the various potentially applicable states' laws.

27. Plaintiff's claims are barred by the additional defenses that may arise during the course of this litigation, which Answering Defendants reserve the right to assert.

28. The matters complained of by Plaintiff, if any, were caused or contributed to, in whole or in part, by the Plaintiff's own negligence and/or comparative responsibility.

29. The acts, omissions, and/or conduct of persons, companies, entities and/or instrumentalities other than Defendants, over which Defendants had no control, was the sole proximate cause of the Plaintiff's alleged injuries, if any.

30. Plaintiff's alleged injuries, if any, were caused or contributed to, in whole or in part, by a party for whom Defendants are not responsible.

31. The acts or omissions of Plaintiff or other third parties were the sole proximate cause or a new and independent cause of the incident and injuries complained of in this lawsuit.

32. The damages in this case, if any, were proximately caused by the negligence of third parties and any recovery should be barred or diminished under the applicable provisions of the law.

33. Defendants further reserve the right to elect that the appropriate percentages of the Plaintiff's alleged injuries and damages be allocated among those parties whose conduct caused the matters complained of by the Plaintiff. Defendants specifically reserve the right to elect to submit to the jury issues of comparative causation and/or comparative negligence and/or comparative responsibility against any settling or non-settling entity as to Plaintiff in this or other suits, as applicable.

34. Defendants specifically assert their rights to an appropriate credit, offset and/or reduction in any liability, which is expressly denied, in the event of a settlement by any party

35. Defendants reserve their right to elect either a pro rata reduction or to take a credit or offset against any judgment against them for any and all sums Plaintiff has received or may hereafter receive in settlement from any party, person or entity, and/or in the alternative assert their right to elect a proportionate reduction of any damages found against them based upon the percentage of negligence, causation, responsibility, or fault attributable to any settling tortfeasor.

36. Defendants further affirmatively deny that they are liable for exemplary damages and relies on the provisions of Chapter 41, of the Texas Civil Practices & Remedies Code, including the provisions on applicability, standards for recovery, preclusions, prejudgment interest, and limitations on amount.

37. An award of punitive damages in this case would violate the procedural due process guaranteed by the Constitution of the United States. Texas Law is vague and standardless as to whether and how much to punish a Defendant, and is likely to produce arbitrary and capricious results. Therefore, any award of punitive damages should be disallowed, or declared null and void.

38. Plaintiff is not entitled to exemplary or punitive damages as alleged, for the reason that exemplary damages are unconstitutional and violate the provisions of the United States Constitution and the Texas Constitution, including but not limited to the following provisions:

- (a) Proscription on excessive fines. U. S. Constitution Amendment 8; Texas Constitution Article I, Section 13.
- (b) Requirements of Due Process. U. S. Constitution Amendments 5 and 14; Texas Constitution Article I, Sections 13 and 19.
- (c) Requirement of Equal Protection Under the Law. U. S. Constitution Amendments 5 and 14; Texas Constitution Article I, Sections 3 and 3a.
- (a) Proscription on Ex Post Facto and Retroactive Law. U. S. Constitution Article I, Section 10; Texas Constitution Article I, Section 16.

- (e) Such punitive damages are penal in nature. Under Texas law, they are not tied to any fair, just, and reasonable relation to actual damages. Consequently, exemplary damages violate the contract clause of the U. S. Constitution, U. S. Constitution Article I, Section 10.

PRAYER

Answering Defendants respectfully request the following relief:

1. That judgment be entered in favor of Answering Defendants and Plaintiff's Complaint be dismissed with Prejudice;
2. That judgment be entered in favor of Answering Defendants for their costs, expenses and reasonable attorneys' fees incurred in connection with this matter; and
3. This Court grant such other and further relief, both at law and in equity, whether general or special, to which they may be justly entitled.

JURY DEMAND

Answering Defendants request trial by a jury of twelve (12).

Respectfully submitted,

Segal McCambridge Singer & Mahoney, Ltd.

Dated: 2/23/07

By: /s Angela Coll Caliendo
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Wal-Mart Stores, Inc.**

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THE QUIGLEY CORPORATION; AND WAL-MART STORES, INC.	:	JUDGE THAD HEARTFIELD
	:	JURY TRIAL REQUESTED
	:	
Defendants.	:	
	:	
	:	

I, Angela Coll Caliendo, Esquire, hereby certify that a true and correct copy of Defendants', The Quigley Corporation and Wal-Mart Stores, Inc. Answer to Plaintiff's First Amended Original Complaint was served via electronic mail and United States First Class Mail addressed to the following individuals on the date shown below:

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Dated: 2/23/07

/s Angela Coll Caliendo

Angela Coll Caliendo, Esquire